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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/867,093	05/29/2001	Eugene Bell	13343-016002	6357

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FISH & RICHARDSON PC
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BOSTON, MA 02110

EXAMINER

ROBINSON, HOPE A

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 07/16/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/867,093

Applicant(s)

BELL ET AL.

Examiner

Hope A. Robinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 15, 16 and 18-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-10, 15, 16, 18-20, 23-33, 35-37, 39, 40, 42, 44, 46 and 48-55 is/are rejected.
- 7) ☐ Claim(s) 21, 22, 34, 38, 41, 43, 45, 47 and 56 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. The Preliminary Amendment filed May 29, 2001 has been received and entered.

Claim Disposition

2. Claims 11-14 and 17 have been canceled. Claims 27-28 and 30 have been amended. Claims 1-10, 15-16 and 18-56 are pending and under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 4, 5, 8, 15, 20, 31, 37, 39, 42, 44, 48, 49 and 53 are rejected under 35 U.S.C. 112 second paragraph, as failing to particularly point out the subject matter which the applicant regards as the invention.

Claim 4 is indefinite as to "between about" as between requires "within" and "about" permits going outside the bounds of the "between". Cancellation of one or the other is suggested (see also Claims 15, 20, 37, 39, 42 and 48). The claim is further indefinite for the recitation of the phrase "between about 1 to 500 um inclusive", because the word inclusive is open language similar to comprising and the word between sets a limit (see also Claims 39, 42 and 48).

Claims 5, 31 and 49 are vague and indefinite for the recitation of the phrase "includes or is conditioned with cells" because it is unclear how a composition is conditioned with cells or how conditioned with cells is an alternative to inclusion of cells.

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Further, how are cells included in the composition? The dependent claims are included in this rejection.

Claim 8 is indefinite because it appears to be an improper Markush claim, as the claim recites, "selected from the group consisting of ligament cells and chrondrocytes and tendon cells. Note that "and" appears twice in the listing. A proper Markush listing is A, B and C or A, B or C (see also Claim 22 where the Markush group has "or" and "and" together in the listing).

Claims 31 and 53 are indefinite because the claims recite "and/or", and it is unclear as to whether the slash refers to "and/or" or just "or".

Claim 44 is indefinite for the recitation of CAPS, TAPS, AMP etc., because the mere recitation of the acronym is insufficient to convey with clarity that which applicant sees as the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 1-10, 15-16, 18-19, 23-33, 35-36, 39-40, 42, 46 and 48-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Bell et al. (U.S. Patent No. 5,891,558, November 21, 1996).

Bell et al. teach compositions mixed with calcium phosphate cement (claim 1) and methods for producing the same (claim 40), for example, -tricalcium phosphate cement which includes 64% -tricalcium phosphate, 16% calcium phosphate monobasic, 15% calcium sulfate hemihydrate (claims 2 and 15) and 5% calcium pyrophosphate (claim 15) to produce a reinforced cement (claim 36) for use as for example, orthopedic or dental implants (claim 3, column 15). Bell et al. teach a density of 300 micrometers, which falls within the range recited in claims 4, 39, 42 and 48 (column 2). Bell et al. teach a method of rebuilding bone, cartilage, tendon, and ligament (claim 46), using foams/foam compositions seeded with the appropriate cells (claim 5), for example, connective tissue cells such as osteocytes (claim 9), chondrocytes, types of mesenchymal cells as recited in claims 6 and 50 (column 8) and tendon and ligament fibrocytes (claim 8), and molded in the appropriate form to repair damaged connective tissue (claim 7, column 1). Bell et al. disclose compositions used in vitro, for example, for model systems for research, or in vivo as prostheses or implants to replace damaged or diseased tissues or to provide scaffolds which, when occupied by cells are remodeled to become functional tissues (see column 1). The reference also teach biocompatible constructs which include single and double density biopolymer foams (claim 29) and extracellular matrix particulates (claim 55) and methods of preparing these constructs which can be used in tissue repair and reconstruction (claim 19, column 3). The extracellular matrix is said to play an instructive role in cell division, morphogenesis, differentiation, tissue building and regeneration (claim 18, columns 11 and 12). Furthermore, the reference teach a preferred biopolymer (claims 23 and 52),

collagen (an injectable vehicle, claims 10 and 51) such as porcine fetal collagen (claims 24 and 25, column 2). In addition, Bell et al. teach single density biopolymer foams (claim 26, column 2). Bell et al. disclose that foam compositions or collagen sponges have been used as hemostatic agents (claims 16 and 53) and more recently as scaffolds (matts, claim 28, column 3) for tissue repair in vivo as research tools and in vitro for seeding various cell types. Further Bell et al. teach microcompartments with walls which include biopolymer fibers and or filaments (claim 27, column 6). Bell et al. teach a composite (claim 32) that consists of conditioned cells (claims 31 and 49, and the ability to contain other structures (claim 30), see column 6. Bell et al. disclose in Example 2, column 20 the use of pepsin in the extraction (claims 33 and 54) of collagen (microfibrillar, claim 35) and buffered solution. Thus, the claims are anticipated by this reference.

Conclusion

5. No claims are presently allowable. Regarding claims 21, 22, 34, 38, 41, 43, 45, 47 and 56, these claims are objected to because they depend from a rejected based claim.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hope A. Robinson whose telephone number is (703)308-6231. The Examiner can normally be reached on Monday - Friday from 9:00 A.M. to 6:00 P.M. (EST).

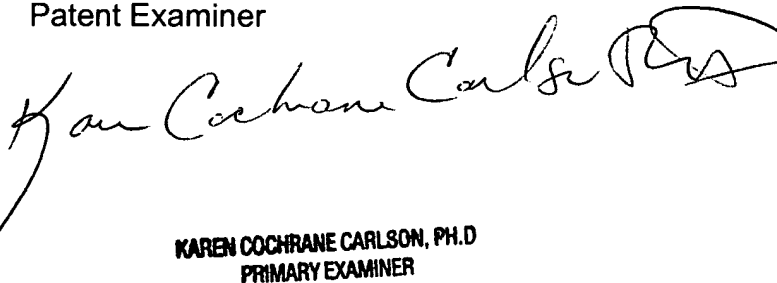
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor Christopher S.F. Low, can be reached at (703)308-2923.

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Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703)308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-4242. Please affix the Examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope A. Robinson, MS 
Patent Examiner


KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER